UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUST LITIGATION	MDL 2724 16-MD-2724
IN RE: LIDOCAINE-PRILOCAINE CASES THIS DOCUMENT RELATES TO: *ALL LIDOCAINE-PRILOCAINE DIRECT PURCHASER ACTIONS*	HON. CYNTHIA M. RUFE LEAD CASE: 16-LD-27240 DIRECT CASE: 16-LD-27241 JURY TRIAL DEMANDED
AHOLD USA, INC.; CÉSAR CASTILLO, INC.; FWK HOLDINGS, L.L.C.; KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC.; and ROCHESTER DRUG CO-OPERATIVE, INC.; on behalf of themselves and all others similarly situated, Plaintiffs, v. AKORN, INC; FOUGERA PHARMACEUTICALS INC.; HI-TECH PHARMACAL CO, INC.; IMPAX LABORATORIES, INC.; and SANDOZ, INC., Defendants.	

CONSOLIDATED DIRECT PURCHASER CLASS ACTION COMPLAINT

REDACTED PUBLIC VERSION
CONTAINS INFORMATION REDACTED PURSUANT
TO MDL 2724 PROTECTIVE ORDER

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I. INTRODUCTION

1. Plaintiffs Ahold USA, Inc., César Castillo, Inc., FWK Holdings, L.L.C., KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc., and Rochester Drug Co-Operative, Inc., on behalf of themselves and all others similarly situated, bring this Class Action Complaint on behalf of a Class (defined below) of direct purchasers who purchased generic lidocaine-prilocaine cream 2.5-2.5% 30gm ("Lidocaine-Prilocaine") directly from Defendants Akorn, Inc, Fougera Pharmaceuticals Inc., Hi-Tech Pharmacal Co., Inc., Impax Laboratories, Inc., or Sandoz, Inc.

2. In the pharmaceutical industry, the entry of generic versions of branded drugs usually results in aggressive price competition, which in turn reduces prices for drug wholesalers, retail pharmacies, consumers, and third party payors. Defendants here, however, conspired to thwart the economic benefits of generic competition.

3. This is a civil action seeking treble damages arising out of the Defendants' unlawful scheme to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation of Lidocaine-Prilocaine. As set forth below, Defendants' scheme violates Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants were not alone in subverting the operation of a competitive marketplace for generic pharmaceuticals. Defendants' anticompetitive conduct in the Lidocaine-Prilocaine market is part of a larger conspiracy or series of conspiracies involving many generic pharmaceutical manufacturers and many generic pharmaceuticals.

4. Plaintiffs' allegations are based on personal knowledge of these matters relating to themselves and upon information and belief as to all other matters. Parts of Plaintiffs' allegations are based on information made public during ongoing government investigations of

Defendants and other generic pharmaceutical companies for alleged unlawful price fixing and other conduct in the generic pharmaceutical industry.

5. Lidocaine-Prilocaine is a combination anesthetic indicated for dermal anesthesia, in other words, it is a combination of two topical anesthetics that is applied to the skin or genital area to cause numbness or loss of feeling before a medical procedure.

6. Lidocaine-Prilocaine has been available in the United States for decades and has been marketed under the brand name EMLA. The market for Lidocaine-Prilocaine is mature.

7. Defendants dominate the market for Lidocaine-Prilocaine. Beginning in approximately March 2014 and continuing today (the "Class Period"), Defendants and co-conspirators engaged in an overarching anticompetitive scheme in the market for Lidocaine-Prilocaine to artificially inflate prices through unlawful agreements. Defendants caused the price of these products to dramatically and inexplicably increase as much as [redacted] higher than February 2014 prices, as alleged in Section V(B)(3) herein. These increases were the result of an agreement among Defendants to increase pricing and restrain competition for the sale of Lidocaine-Prilocaine cream in the United States.

8. Defendants orchestrated their conspiracy through secret communications and meetings, both in private and at public events, such as trade association meetings held by the Generic Pharmaceutical Association ("GPhA") (now called the Association for Accessible Medicines),[1] the Healthcare Distribution Management Association ("HDMA") (now called the Healthcare Distribution Alliance), the Minnesota Multistate Contracting Alliance for Pharmacy ("MMCAP"), the National Association of Chain Drug Stores ("NACDS"), Efficient

[1] *See* Russell Redman, *New name for Generic Pharmaceutical Association*, CHAIN DRUG REVIEW (Feb. 14, 2017), *available at* http://www.chaindrugreview.com/new-name-for-generic-pharmaceutical-association/.

Collaborative Retail Marketing ("ECRM"), and the National Pharmacy Forum ("NPF"), among others.

9. Defendants' and other generic pharmaceutical manufacturers' conduct has resulted in extensive scrutiny by federal and state regulators, including by the Antitrust Division of the United States Department of Justice ("DOJ"), the United States Senate, the United States House of Representatives, and at least 45 attorneys general from 44 states and the District of Columbia (the "State AGs"). The DOJ empaneled a federal grand jury in this District, which has issued subpoenas relating to price fixing and other anticompetitive conduct in the generic pharmaceutical industry, including to Defendants Impax and Sandoz.

10. The DOJ's and State AGs' investigations followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA") January 2014 correspondence to the United States Senate Health Education Labor and Pensions ("HELP") Committee and the United States House Energy and Commerce Committee requesting hearings on significant spikes in generic pharmaceutical pricing.[2] The NCPA's news release reported price hikes on essential generic pharmaceuticals exceeding 1,000% in some instances, according to its survey of over a thousand community pharmacists, resulting in some patients being forced to leave their prescriptions at the pharmacy counter due to increased copays, and forcing more seniors into Medicare's coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs.

11. On December 12 and 13, 2016, the DOJ filed its first criminal charges against two former executives of Heritage Pharmaceuticals: Jeffrey Glazer and Jason Malek. *See United*

[2] News Release, *Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say* (Jan. 8, 2014), *available at* http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say.

States of America v. Jeffrey A. Glazer, No. 2:16-cr-00506-RBS (E.D. Pa.); *United States of America v. Jason T. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa.). The DOJ alleged that both Glazer and Malek conspired with others "to allocate customers, rig bids, and fix and maintain prices" of generic glyburide and doxycycline sold in the United States. Each was charged with two felony counts under the Sherman Act, 15 U.S.C. § 1. On January 9, 2017, both Glazer and Malek pleaded guilty to the charges. They continue to cooperate with the DOJ's ongoing investigation as they await sentencing.

12. The DOJ has publicly acknowledged that its investigation overlaps with MDL 2724. For example, the DOJ filed a motion for a stay of discovery in MDL 2724 noting that:

> Evidence uncovered during the criminal investigation implicates other companies and individuals (including a significant number of the Defendants here) in collusion with respect to doxycycline hyclate, glyburide, and other drugs (including a significant number of the drugs at issue here).[3]

13. Soon after the DOJ filed criminal charges, 20 state attorneys general led by the State of Connecticut also sued generic manufacturers Aurobindo, Citron, Heritage, and Teva, as well as Mayne and Mylan for bid rigging, price-fixing and market and customer allocation in connection with their sale of generic glyburide and doxycycline in the United States. On March 1, 2017, the complaint in the State AG action was amended to, *inter alia*, add claims of an additional 20 state attorneys general, bringing the total number of State AGs prosecuting the action to 40. Glazer and Malek entered into settlement agreements with the attorneys general on March 16, 2017.[4] Commenting on the scope of its current antitrust investigation, the

[3] *See* Intervenor United States' Motion to Stay Discovery, *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724, ECF 279 (E.D. Pa. May 1, 2017).

[4] John Kennedy, *Ex-Heritage Execs to Help States Probe Drug Price-Fixing*, LAW360 (May 24, 2017), *available at* https://www.law360.com/competition/articles/927899/ex-heritage-

Connecticut Attorney General ("CTAG") George Jepsen stated that "[t]he issues we're investigating go *way beyond* the two drugs and six companies. *Way beyond…We're learning new things every day*."[5] On July 17, 2017, 5 additional attorneys general joined the action by filing a nearly identical complaint and a notice of related case.[6]

14. As noted above, the State AGs' and DOJ's investigations are ongoing. Just last week, Pfizer Inc. reported in an SEC filing dated August 10, 2017 that:

> As of July 2017, the U.S. Department of Justice's Antitrust Division is investigating our Greenstone generics business. We believe this is related to an ongoing antitrust investigation of the generic pharmaceutical industry. The government has been obtaining information from Greenstone.

15. As a result of Defendants' scheme to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation of Lidocaine-Prilocaine, direct purchasers paid, and continue to pay, supracompetitive prices for Lidocaine-Prilocaine.

16. Plaintiffs, on behalf of themselves and members of a direct purchaser class, seek damages caused by Defendants' and co-conspirators' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

II. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action as it arises under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Section 4 of the Clayton Act, 15 U.S.C. § 15. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).

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execs-to-help-states-probe-drug-price-fixing?nl_pk=eb0b62b3-08e3-46ed-ac8a-7ab5fa616c07&utm_source=newsletter&utm_medium=email&utm_campaign=competition.

[5] Liz Szabo, et al., *How Martinis, Steaks, and a Golf Round Raised Your Prescription Drug Prices*, THE DAILY BEAST (Dec. 21, 2016), *available at* http://thebea.st/2haV9xg (emphasis added).

[6] *Arkansas v. Aurobindo Pharma USA, Inc.*, No. 17-cv-1180 (D. Conn.).

18. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(b), (c), and (d), because during the Class Period Defendants transacted business throughout the United States, including in this District, Defendants resided, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

19. During the Class Period, Defendants sold and distributed generic pharmaceuticals in a continuous and uninterrupted flow of interstate commerce, which included sales of Lidocaine-Prilocaine in the United States, including in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

20. This Court has personal jurisdiction over each Defendant because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of Lidocaine-Prilocaine throughout the United States, including in this District; (c) had and maintained substantial contacts within the United States, including in this District; and/or (d) was engaged in an unlawful conspiracy to inflate the prices for Lidocaine-Prilocaine that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

III. PARTIES

A. Plaintiffs

21. Plaintiff Ahold USA, Inc. ("Ahold") is a Maryland corporation with its principal places of business in Quincy, Massachusetts and Carlisle, Pennsylvania. During the Class Period, Ahold purchased Lidocaine-Prilocaine directly from one or more Defendants. As a result

of Defendants' antitrust conspiracy, Ahold paid supracompetitive prices for its Lidocaine-Prilocaine purchases and was injured by the illegal conduct alleged herein.

22. Plaintiff César Castillo, Inc. ("CCI") is a Puerto Rico corporation with its principal place of business in Rio Piedras, Puerto Rico. During the Class Period, CCI purchased Lidocaine-Prilocaine directly from one or more Defendants. As a result of Defendants' antitrust conspiracy, CCI paid supracompetitive prices for its Lidocaine-Prilocaine purchases and was injured by the illegal conduct alleged herein.

23. Plaintiff FWK Holdings, LLC ("FWK") is an Illinois corporation with its principal place of business in Glen Ellyn, Illinois. FWK is the assignee of antitrust claims possessed by Frank W. Kerr Company ("Kerr") and brings this action as successor-in-interest to Kerr's claims arising from its purchase of Lidocaine-Prilocaine directly from one or more of the Defendants during the Class Period. As a result of Defendants' antitrust conspiracy, FWK, through assignor Kerr, paid supracompetitive prices for its Lidocaine-Prilocaine purchases and was injured by the illegal conduct alleged herein.

24. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a New York corporation with its principal place of business in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. During the Class Period, KPH directly purchased Lidocaine-Prilocaine from one or more of the Defendants. As a result of Defendants' antitrust conspiracy, KPH paid supracompetitive prices for its Lidocaine-Prilocaine purchases, and KPH was injured by the illegal conduct alleged herein.

25. Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a New York corporation with its principal place of business in Rochester, New York. During the Class Period, RDC

purchased Lidocaine-Prilocaine directly from one or more of the Defendants at artificially and unlawfully inflated prices. As a result of Defendants' antitrust conspiracy, RDC paid supracompetitive prices for its Lidocaine-Prilocaine purchases, and RDC was injured by the illegal conduct alleged herein.

B. Defendants

26. Defendant Akorn, Inc. ("Akorn") is a Louisiana corporation with its principal place of business in Lake Forest, Illinois. During the Class Period, Akorn marketed and sold Lidocaine-Prilocaine to purchasers in this District and throughout the United States.

27. Defendant Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") is a Delaware corporation with its principal place of business in Amityville, New York. During the Class Period, Hi-Tech marketed and sold Lidocaine-Prilocaine to purchasers in this District and throughout the United States. Hi-Tech became a subsidiary of Akorn in April 2014 when Akorn completed its acquisition of Hi-Tech for $640 million.

28. Defendant Impax Laboratories, Inc. ("Impax") is a Delaware corporation with its principal place of business in Hayward, California. During the Class Period, Impax manufactured and distributed Lidocaine-Prilocaine through its Global Pharmaceuticals division. During the Class Period, Impax marketed and sold Lidocaine-Prilocaine to purchasers in this District and throughout the United States.

29. Defendant Sandoz Inc. ("Sandoz") is a Colorado corporation with its principal place of business in Princeton, New Jersey. During the Class Period, Sandoz developed, manufactured, and marketed prescription drugs, including Lidocaine-Prilocaine throughout the United States.

30. Defendant Fougera Pharmaceuticals Inc. ("Fougera") is a New York corporation with its principal place of business in Melville, New York. Fougera is a specialty dermatology

generic pharmaceutical company and a wholly owned subsidiary of Defendant Sandoz, Inc. In this Complaint, Fougera and Sandoz will be referred to collectively as "Sandoz." Sandoz marketed and sold Lidocaine-Prilocaine to purchasers in this District and throughout the United States.

31. Defendants and their officers, agents, employees, or representatives have engaged in the conduct alleged in this Complaint while actively involved in the management of Defendants' business and affairs.

C. Co-Conspirators

32. Various other persons, firms, entities, and corporations, not named as Defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged herein, and have aided, abetted, and performed acts and made statements in furtherance of the conspiracy.

33. The true names and capacities of additional co-conspirators, whether individual, corporate, associate, or representative, are presently unknown to Plaintiffs. Plaintiffs may amend this Complaint to allege the true names and capacities of additional co-conspirators as they are discovered.

34. At all relevant times, other persons, firms, and corporations, referred to herein as "co-conspirators," the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful scheme as described herein.

35. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

36. The wrongful acts alleged to have been done by any one Defendant or co-conspirator were authorized, ordered, or done by its directors, officers, managers, agents, employees, or representatives while actively engaged in the management, direction, or control of such Defendant's or co-conspirator's affairs.

IV. INTERSTATE TRADE AND COMMERCE

37. Defendants are the leading manufacturers and suppliers of Lidocaine-Prilocaine sold in the United States.

38. Lidocaine-Prilocaine is produced by or on behalf of Defendants or their affiliates in the United States or overseas.

39. During the Class Period, Defendants, directly or through one or more of their affiliates, sold Lidocaine-Prilocaine throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

40. The activities of Defendants and their co-conspirators were within the flow of, intended to, and had a substantial effect on interstate commerce in the United States.

41. Defendants' and their co-conspirators' conduct, including the marketing and sale of Lidocaine-Prilocaine, took place within, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

42. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce in that Defendants deprived Plaintiffs of the benefits of free and open competition in the purchase of Lidocaine-Prilocaine within the United States.

43. Defendants' agreement to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation of Lidocaine-Prilocaine, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Lidocaine-Prilocaine prices, were intended to have,

and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States.

V. FACTUAL ALLEGATIONS

A. The Generic Drug Market Is a Commodities Market, Where Competition Historically Has Been Keen.

1. Generic drugs should lead to lower prices.

44. Generic drugs provide a lower-cost but bioequivalent alternative to brand drugs. Before any generic drug can be marketed, the Food and Drug Administration (the "FDA") requires rigorous testing to ensure it has the same strength, quality, safety, and performance as the brand. By law, generics must have the same amount of active ingredient and must be "therapeutically equivalent" to the brand, meaning they must meet exacting bioequivalence testing specifications so patients can expect "equal effect and no difference when [generics are] substituted for the brand name product."[7]

45. To encourage the production and sale of generic drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") simplified the regulatory hurdles that generic pharmaceutical manufacturers have to clear before marketing and selling generic pharmaceuticals. Instead of filing a lengthy and costly New Drug Application, the Hatch-Waxman Act allows generic pharmaceutical manufacturers to obtain FDA approval in an expedited fashion.

46. To obtain marketing approval for a generic pharmaceutical, an Abbreviated New Drug Application ("ANDA") must be filed with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs; "abbreviated" because so long as the ANDA includes data

[7] FDA, *Drugs@FDA Glossary of Terms*, *available at* http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G.

showing bioequivalence to the brand, the ANDA sponsor can reference efficacy data supporting approval of the brand (described in the regulations as the "Reference Listed Drug" or "RLD" for short) instead of repeating all the same clinical trials. Upon the FDA's determination that bioequivalence to the brand has been established, the ANDA will be approved and may be marketed in the United States as substitutable with the RLD.

47. Although equivalent from a safety and efficacy standpoint, generic versions of brand name drugs are priced significantly below their brand counterparts, and because of this, they rapidly gain market share from the brand beginning immediately following launch. Indeed, in every state, pharmacists are permitted (and in many states required) to substitute a generic product for a brand product barring a note from a doctor that the brand product must be dispensed as written.

48. It is well established in economic literature that competition by generic products results in lower prices for drug purchasers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price free from competitive market forces. But once the first lower-priced generic enters, a brand drug rapidly loses sales due to automatic pharmacy counter substitution, and generics capture as much as 80% of the market or more within months of launch. And as more generics become available, generic prices only decline further due to competition among generics. These cost reductions to drug purchasers were the very legislative purpose behind the abbreviated regulatory pathway for generic approval under the Hatch Waxman Act.

49. Generic competition, under lawful and competitive circumstances, reduces drug costs by driving down the prices of both generic versions of the brand drug and often the brand

drug itself, and every year generic drugs result in hundreds of billions of dollars in savings to consumers, insurers, and other drug purchasers.

50. A Federal Trade Commission study found that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[8] A mature generic market, such as the market for Lidocaine-Prilocaine, has several generic competitors. Because each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.[9] Over time, generics' pricing nears the generic manufacturers' marginal costs.

51. Generic competition usually enables purchasers to purchase generic versions of the brand drug at a substantially lower price than the brand drug. Generic competition to a single blockbuster brand drug can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic drugs saved the United States healthcare system $1.68 trillion between 2005 and 2014.[10]

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[8] Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 8 (Jan. 2010), *available at* https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff.

[9] *See, e.g.*, Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at 17 (Aug. 2011) ("[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."), *available at* https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission; U.S. Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Proceed and Returns in the Pharmaceutical Industry* (July 1998), *available at* https://www.cbo.gov/publication/10938.

[10] GPhA, GENERIC DRUG SAVINGS IN THE U.S. (7th ed. 2015) at 1, *available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

2. Prescription drug prices in the United States are governed by institutional safeguards, which are intended to keep drug prices competitive.

52. Ordinarily, the price for a consumer product is set by the retailer based on the amount the typical consumer is willing to pay. But because of the unique features of the prescription drug marketplace, prescription drug pricing for most consumers is not determined between the retailer and the consumer. Rather, because most consumers' prescription drug purchases are reimbursed by public or private health plans, consumer pricing for prescription drugs is determined by reimbursement agreements between these prescription drug payers, *i.e.*, health plans and their prescription benefit managers, and the pharmacies that dispense drugs to the payers' insured customers.

53. Generic manufacturers typically report a Wholesale Acquisition Cost ("WAC") for their drugs. WAC prices represent the manufacturer's benchmark or reported list price. The WAC typically functions as the manufacturer's list or benchmark price in sales to wholesalers or other direct purchasers and typically does not include discounts that may be provided, *e.g.*, for volume sales. Manufacturers generally provide their WACs to purchasers or report them to publishers that compile that information for the market.[11]

54. Generic drug manufacturers may charge different amounts for an equally interchangeable, *i.e.*, therapeutically equivalent, multisource drug. But manufacturers are usually constrained in their ability to price generic drugs by the Maximum Allowable Cost ("MAC").[12]

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[11] At one time, payors relied on cost-based pricing metrics to reimburse pharmacies that dispensed drugs to their insured customers, paying the dispensing pharmacies an amount based on the manufacturer's list price for the drug, plus a small mark-up or dispensing fee. Over time, however, it was learned that the list price for most generic drugs published by their manufacturers was substantially higher than the actual cost incurred by pharmacies to acquire the drugs.

[12] To define therapeutic categories, MAC pricing typically relies on the FDA's Orange Book, which lists approved prescription drugs and their therapeutic equivalents. An "A"-rated

MAC is a contractually based payment model that, in the private sector, is commonly established by a pharmacy benefits manager ("PBM"), who manages an insurance plan, and that is paid to the pharmacies within the plan's network.[13] A MAC price sets the upper limit that a pharmacy will be paid by the PBM for procuring and dispensing a particular generic medication.

55. While PBMs usually do not disclose publicly which drugs they subject to MAC pricing, what the MAC price is, or what factors they apply to set MAC prices, it is believed that PBMs rely on a wide-variety of market-wide pricing information or plan-specific data.[14] In recent years, 79% of employer prescription drug plans and 45 state Medicaid programs have been using MAC prices to control the cost of generic drugs.[15] MAC prices give pharmacies an incentive to procure and dispense the lowest-priced drug product available for a particular multisource drug. If a generic drug is subject to MAC pricing, a pharmacy purchasing a higher-priced generic product will make less profit or potentially even lose money when it dispenses a higher-priced product.[16]

56. MAC pricing is neither uniform, nor transparent and may be subject to frequent changes. So whether a generic manufacturer's products are even subject to MAC pricing or how

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drug is one that the FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products. *See* U.S. FDA Website, Orange Book Preface, *available at* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#tecode.

[13] Academy of Managed Care Pharmacy, *Where We Stand, Maximum Allowable Cost (MAC) Pricing* (Dec. 2013), *available at* www.amcp.org/Sec.aspx?id=9287. For the purposes of this complaint, MAC prices refer solely to prices that limit a pharmacy's reimbursement for generic drugs, not the amounts PBMs charge to the insurance plans, which may also be referred to as a MAC price. *See* National Community Pharmacists Association, *The Need for Legislation Regarding "Maximum Allowable Cost" (MAC) Reimbursement*, *available at* http://www.ncpa.co/pdf/leg/mac-one-pager.pdf.

[14] *Id.*

[15] Express Scripts, *MAC Pricing lncents More Affordable Rx* (Feb. 24, 2016), *available at* http://lab.express-scripts.com/lab/insights/drug-options/mac-pricing-incents-more-affordable-rx.

[16] *See supra* Academy of Managed Care Pharmacy article.

that MAC pricing is set for any particular generic drug is not easy for the manufacturers to decipher. PBMs typically exercise control over the selection of generic medications that will be subjected to MAC pricing, and they fiercely guard the secrecy of their MAC price lists.[17] Industry groups, like the Academy of Managed Care Pharmacy, actively oppose government regulation of MAC pricing and any efforts to disclose MAC prices or the method of calculating them.[18]

57. By setting a ceiling for reimbursement of any particular generic drug at the pharmacy level, MAC prices indirectly affect the price at which generic drug manufacturers may sell their products to direct purchasers. Because many generic drugs are subject to MAC pricing, generic drug manufacturers have an incentive to price their generic drug products competitively to maintain demand by pharmacies.

58. MAC pricing can penalize the generic drug manufacturer that raises price on its own when its competitors do not. A unilateral price increase in a competitive generic drug market that is subject to MAC pricing is likely to send buyers to a lower-price alternative. MAC pricing has little effect if generic drug manufacturers collectively increase their prices for a multi-source drug. First, PBMs generally permit pharmacies—who may be contractually obligated to dispense an unprofitable prescription—to challenge MAC prices under a MAC appeals process.[19] If the price of a generic drug has been increased by the majority of generic drug manufacturers, then these MAC appeals may be successful in getting the PBM to increase the MAC price allowed. Second, PBMs typically have a policy of revising MAC prices under

[17] *See supra* National Community Pharmacists Association article.

[18] *See supra* Academy of Managed Care Pharmacy article.

[19] *Id.*

certain contingencies.[20] One large PBM, Express Scripts, for example, states that its MAC price list is frequently updated to reflect "the current market dynamics."[21]

59. MAC pricing provides yet another reason that Defendants' stark increases in the price of Lidocaine-Prilocaine are indicative of coordinated pricing activity. Knowing that they hold an overwhelming majority share of the market for Lidocaine-Prilocaine, Defendants had the capacity to dictate the market price and to influence the MAC prices set by PBMs, but only if they acted collectively. Absent collusion, individual Defendants could not have increased their prices to the high levels they did (or maintain high prices in the face of a significantly lower competitor price) without incurring the loss of a significant volume of sales.

B. Defendants' Conspired, Among Other Things, to Raise Lidocaine-Prilocaine Prices.

1. Defendants' dominance over Lidocaine-Prilocaine sales permitted them to fix prices, and their abrupt price increases are otherwise inexplicable.

60. The market for Lidocaine-Prilocaine is mature, as generic versions have been on the market for years. In 2015 alone, Defendants' total revenue from direct sales of these products was approximately [redacted].[22] This compares to only [redacted] in 2013, a year before the price fixing conspiracy.

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[20] *Id.*

[21] *See supra* Express Scripts article.

[22] Revenue, unit sales, and effective prices are obtained from QuintilesIMS Inc. ("IMS Health"). IMS Health is the largest vendor of physicians' prescribing data in the United States and is widely relied upon in the pharmaceutical industry and elsewhere. As used in this complaint, "effective prices" represent actual transaction prices, as reported by IMS Health. Plaintiffs calculate Defendants' effective prices based on IMS Health's National Sales Perspectives ("NSP") data, which "captures 100% of the total U.S. pharmaceutical market, measuring sales at actual transaction prices[.]" IMS Institute for Healthcare Informatics, HSRN Data Brief: National Sales Perspectives, at 1, *available at* https://www.imshealth.com/files/web/IMSH%20Institute/NSP_Data_Brief-.pdf.

Effective prices are calculated to multiple decimals. For ease of reference, prices in this complaint are rounded to the nearest cent. However, percentage increases are calculated based on the more precisely calculated price.

61. A mature generic market, such as the market for Lidocaine-Prilocaine, has several generic competitors. As noted above, because each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers. In a market free from collusive activity, over time, generics' pricing would naturally near (and stay near) the generic manufacturers' marginal costs.

62. At all times relevant for this lawsuit, there have been multiple manufacturers of Lidocaine-Prilocaine on the market. Under accepted economic principles of competition, when there are multiple generics on the market, prices should remain at highly competitive, historic levels, and should not increase starkly as they did here absent anticompetitive conduct. Drastic increases in Lidocaine-Prilocaine prices are themselves suggestive of Defendants' collective market dominance: if they did not already dominate the market, Defendants' pricing excesses would be disciplined because they would lose market share to non-colluding competitors.

2. Defendants' collective market dominance permitted them to collude.

63. During the Class Period, the Defendants dominated the market and held roughly [redacted] of the market in March 2014, when the price fixing conspiracy began.[23]

64. In terms of revenue, in 2015, Defendant Akorn's sales to direct purchasers were roughly [redacted], Defendant Impax about [redacted], Defendant Hi-Tech about [redacted], and Defendant Sandoz about [redacted].

3. Defendants' effective prices were remarkably stable before skyrocketing in the Class Period.

65. Before the Class Period, aside from a few brief aberrations, the effective prices of Defendants' Lidocaine-Prilocaine remained stable for years, as is typical in a mature market.

[23] Market share is calculated in this complaint by reference to IMS unit sales data.

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

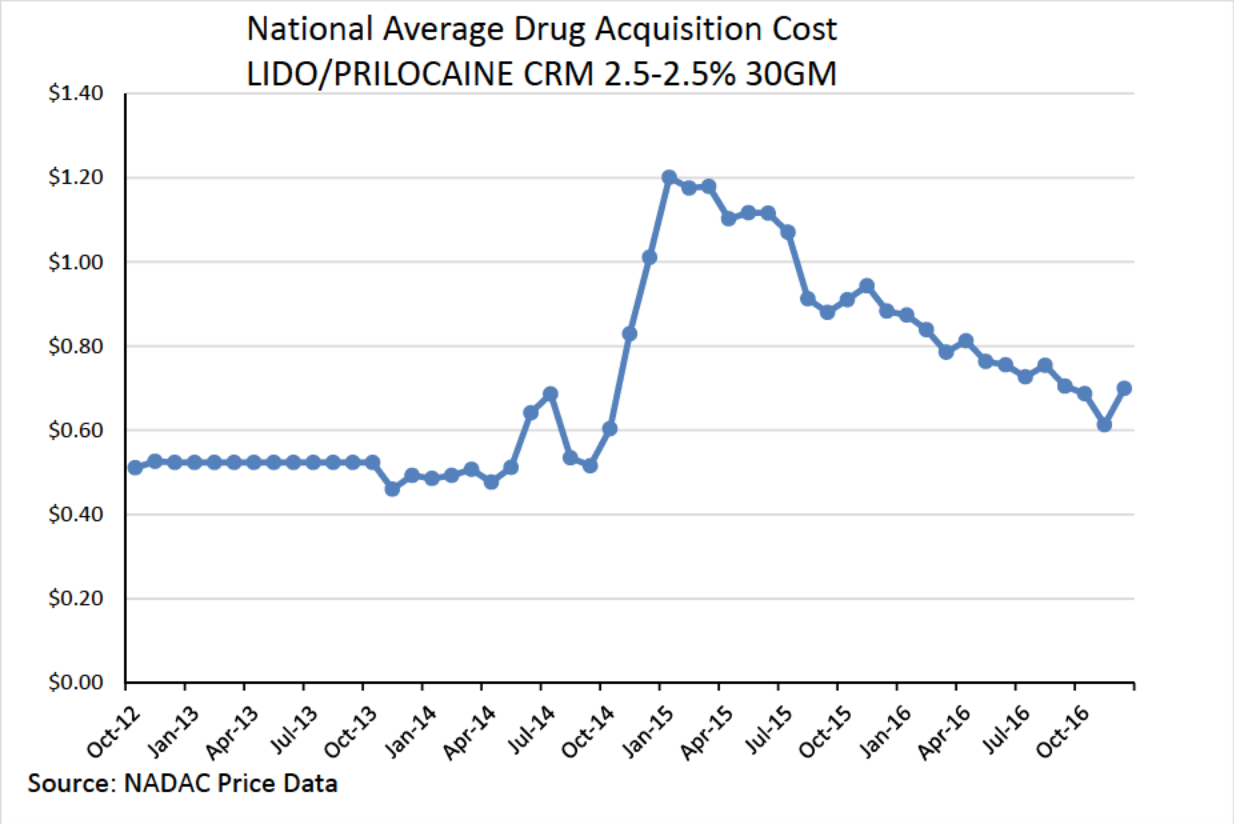
[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

83. Defendants' price increases coincide with increases reported by the Centers for Medicare & Medicaid Services:



4. There are no shortages or other market changes that would justify Defendants' price increases.

84. During the Class Period, there was no significant increase in the costs of making Lidocaine-Prilocaine, no significant decrease in supply, and no significant increase in demand. Nonetheless, there were extraordinary increases by each of the Defendants in the prices they charged their customers for Lidocaine-Prilocaine. Such price increases in a commodity product for which there were no significant increases in costs or demand and no significant decrease in supply would not have been in each Defendant's unilateral self-interest absent the existence of a cartel.

85. Federal law requires that drug manufacturers report drug shortages.[24] Lidocaine-Prilocaine is not listed on the FDA's list of Current and Resolved Drug Shortages and Discontinuations Reported to FDA. Lidocaine-Prilocaine also does not appear on any archived lists of the American Society of Health-System Pharmacists ("ASHP") Current Shortage Bulletins from July 3, 2012, through today, nor does it appear on the current list of ASHP Resolved Shortage Bulletins (which includes drug shortages dating back to August 2010). None of the Defendants reported any drug shortages or supply disruptions to the FDA in explanation for the supracompetitive pricing of Lidocaine-Prilocaine.

86. Nor does any change in the marketplace explain the rising prices—before the Class Period, from March 2011 through February 2014, Defendants accounted for around [redacted] of the direct sales of Lidocaine-Prilocaine. During the Class Period, Defendants maintained roughly [redacted] of the market even after an authorized generic version of the drug began to be sold by Teva in April 2015, a full year after the price increase.

C. Defendants Orchestrated Their Conspiracy Through In-Person Meetings and Other Forms of Communication.[25]

87. During the Class Period, Defendants conspired, combined, and contracted to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation concerning Lidocaine-Prilocaine, which had the intended and actual effect of causing Plaintiffs and the other members of the proposed Class to pay artificially inflated prices above prices that would exist if a competitive market had determined prices for Lidocaine-Prilocaine.

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[24] FDA Safety and Innovation Act of 2012, Pub. L. No. 112-144, §§ 1001-1008, 126 STAT. 995, 1099-1108.

[25] The allegations included in this section pertaining to the HDMA, NACDS, and ECRM are based in part upon documents produced to plaintiffs pursuant to subpoenas *duces tecum* issued in *In re: Propranolol Antitrust Litig.*, No. 16-cv-9901 (S.D.N.Y.).

88. Beginning in March 2014, Defendants collectively caused the price of Lidocaine-Prilocaine to increase dramatically. Defendants' conduct cannot be explained by normal competitive forces. It was the result of an agreement among Defendants to increase pricing and restrain competition for the sale of Lidocaine-Prilocaine in the United States. The agreement was furthered by discussions held at meetings and industry events hosted by the GPhA, HDMA, NACDS, and ECRM as well as other meetings and communications.

89. In formulating and effectuating their conspiracy, Defendants engaged in numerous anticompetitive activities, including, among other things:

(a) Participating, directing, authorizing, or consenting to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to discuss the sale and pricing of Lidocaine-Prilocaine in the United States;

(b) Participating, directing, authorizing, or consenting to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to engage in market and customer allocation or bid rigging for Lidocaine-Prilocaine sold in the United States;

(c) Agreeing during those meetings, conversations, and communications to engage in market and customer allocation or bid rigging for Lidocaine-Prilocaine sold in the United States;

(d) Agreeing during those meetings, conversations, and communications not to compete against each other for certain customers for Lidocaine-Prilocaine sold in the United States;

(e) Submitting bids, withholding bids, and issuing price proposals in accordance with the agreements reached;

(f) Selling Lidocaine-Prilocaine in the United States at collusive and noncompetitive prices; and

(g) Accepting payment for Lidocaine-Prilocaine sold in the United States at collusive and noncompetitive prices.

90. To sustain a conspiracy, conspirators often communicate to ensure that all are adhering to the collective scheme. Here, such communications occurred primarily through (1)

trade association meetings and conferences, (2) private meetings, dinners, and outings among smaller groups of employees of various generic drug manufacturers, and (3) individual private communications between and among Defendants' employees through use of the phone, electronic messaging and similar means.

91. These secret, conspiratorial meetings, discussions, and communications helped to ensure that all Defendants agreed to participate in, implement, and maintain an unlawful bid rigging, price-fixing, and market and customer allocation scheme.

92. The industry intelligence-gathering reporting firm *Policy and Regulatory Report* has reportedly obtained information regarding the investigation of generic drug companies by the DOJ, and has indicated that the DOJ is investigating the extent to which trade associations and industry conferences have been used as forums for collusion among competing generic drug companies.[26] The State AGs have similarly noted the centrality of trade associations and industry conferences in their investigation stating that they have uncovered evidence that certain generic drug companies "routinely coordinated their schemes through direct interaction with their competitors at industry trade shows, customer conferences, and other events, as well as through direct email, phone, and text message communications."[27]

93. Defendants were members of numerous trade associations, which they used to facilitate their conspiratorial communications and implement their anticompetitive scheme to raise, maintain, and stabilize the prices of Lidocaine-Prilocaine, rig bids, and engage in market

[26] Eric Palmer, *Actavis gets subpoena as DOJ probe of generic pricing moves up food chain*, FIERCEPHARMA (Aug. 7, 2015), *available at* http://www.fiercepharma.com/story/actavis-gets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07.

[27] CTAG Website, Press Release, *40 State Attorneys General Now Plaintiffs in Federal Generic Drug Antitrust Lawsuit* (Mar. 1, 2017), *available at* http://www.ct.gov/ag/cwp/view.asp?Q=588538&A=2341.

and customer allocation concerning Lidocaine-Prilocaine, including, but not limited to, GPhA, the NACDS, and HDMA. [redacted]

94. The GPhA (now called the Association for Accessible Medicines) is the "nation's leading trade association for manufacturers and distributors of generic prescription drugs . . . ."[28] GPhA was formed in 2000 from the merger of three industry trade associations: the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

95. GPhA's website touts, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry" and lists its "valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections."[29] GPhA's "member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year."

96. Defendants Impax and Sandoz were regular members of the GPhA during the Class Period. Regular members "are corporations, partnerships or other legal entities whose primary U.S. business derives the majority of its revenues from sales of (1) finished dose drugs approved via ANDAs; (2) products sold as authorized generic drugs; (3) biosimilar/biogeneric products; or (4) DESI products."[30]

97. Several of Defendants high-ranking corporate officers have served on GPhA's Board of Directors before and during the Class Period:

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[28] GPhA, *Membership*, http://web.archive.org/web/20150413013008/http:/www.gphaonline.org:80/about/membership.

[29] *Id.*

[30] *Id.*

98. **2012 Board of Directors**: David Klaum, Sr. VP & GM, Fougera; Carol Ben-Maimon, President, Impax Global Pharmaceuticals; and Don DeGolyer, President and CEO, Sandoz;

99. **2013 Board of Directors**: Carol Ben-Maimon, President, Impax Global Pharmaceuticals; and Don DeGolyer, President and CEO, Sandoz;

100. **2014 Board of Directors**: Carol Ben-Maimon, President, Impax Global Pharmaceuticals; Peter Goldschmidt, President of Sandoz US.

101. **2015 Board of Directors**: Marcy McDonald, VP Regulatory Affairs of Impax; Peter Goldschmidt, President of Sandoz US; and

102. **2016 Board of Directors**: Marcy McDonald, VP Regulatory Affairs of Impax; and Peter Goldschmidt, President of Sandoz US.

103. In addition, former Heritage CEO, Jeffrey Glazer, who pleaded guilty to federal criminal charges relating to the price fixing and other anticompetitive activity concerning generic drugs, also served on GPhA's board of directors.

104. The NACDS is a national trade association representing chain community pharmacies. Its members include generic drug manufacturers, wholesalers, and retail chain pharmacies. NACDS holds regular industry events, including annual and regional conferences, which Defendants and other generic drug manufacturers attended, including the annual Total Store Expo.

105. The HDMA (now called HDA) is a national trade association that represents "primary pharmaceutical distributors" which links the nation's drug manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, and clinics.[31] HDMA holds regular

[31] HDA, About, *available at* https://www.healthcaredistribution.org/about.

conferences where its members, including generic drug manufacturers, meet to discuss various issues affecting the pharmaceutical industry. HDMA members during the Class Period have included Defendants Impax and Sandoz.

106. According to its website, ECRM conducts Efficient Program Planning Sessions that are made up of one-on-one strategic meetings that connect decision makers in an effort to maximize time, grow sales, and uncover industry trends.

107. At annual meetings organized by ECRM, generic drug manufacturers have scheduled meetings with generic drug buyers at chain drug stores, supermarkets, mass merchants, wholesalers, distributors, and buy groups for independents.

[redacted]

109. As further set forth below, meetings and events hosted by the GPhA, HDMA, NACDS, and ECRM were frequently held during the Class Period and attended by high-level representatives from each Defendant, including employees with price-setting authority.

110. For example, on October 1-3, 2012, GPhA held a meeting in Bethesda, Maryland that was attended by representatives of at least Defendants Fougera, Impax, and Sandoz.

111. On February 20-22, 2013, GPhA held its Annual Meeting in Orlando, Florida that was attended by at least Defendants Akorn, Impax, and Sandoz.

[redacted]

a. [redacted]

b. [redacted]

113. On June 4-5, 2013, GPhA held a meeting in Bethesda, Maryland that was attended by at least Defendants Fougera, Hi-Tech, Impax, and Sandoz.

114. On June 2-5, 2013, HDMA held its 2013 Business Leadership Conference "BLC" in Orlando, Florida. HDMA's June 2013 BLC was attended by at least the following representatives from Defendants, who were key executives for generic drug sales and pricing:

a. **Akorn:** Mark Dudick, Senior Director, National Accounts;

a. **Impax**: Danny Darnell, Sr. National Account Manager; Gary Skalski, Director of Sales; Michael Grigsby, Sr. National Accounts Manager; Todd Engle, Sr. Director Sales Operations; William Ball, Sr. National Accounts Manager; and

b. **Sandoz**: Alan Ryan, Associate Director, National Accounts; Dawn Doggett, National Trade Affairs Account Executive.

115. On August 10-13, 2013, NACDS held its 2013 Total Store Expo at the Sands Expo Convention Center in Las Vegas, Nevada. NACDS's August 2013 Total Store Expo was

attended by the following representatives from all Defendants, including at least the following key executives for generic drug sales and pricing:

a. **Akorn:** M. Tranter, National Accounts Manager, Sales & Marketing; John Sabat, Senior VP, National Accounts; Mick McCanna, Account Manager;

b. **Hi-Tech**: Ed Berrios, VP Sales & Marketing; Michael Corley, VP, National Accounts; Thomas Kronovich, VP National Accounts;

c. **Impax**: Chris Gerber, Director of Pricing and Contracts; Italo Pennella, Trade Account Manager; Dan Rozmiarek, Trade Account Manager; and

d. **Sandoz**: Peter Goldschmidt, President, Sandoz USA and Head, NA; Steven Greenstein, Director, Key Customers; Anuj Hasija, Executive Director, Key Customers; Armando Kellum, VP Sales & Marketing; Paul Krauthauser, SVP, Sales & Marketing; Della Lubke, National Account Executive.

116. On October 28-30, 2013, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from all Defendants, including Akorn, Fougera, Hi-Tech, Impax, and Sandoz.

117. On February 28-30, 2013, GPhA held its Annual Meeting in Orlando, Florida that was attended by representatives from at least Defendants Hi-Tech, Impax, and Sandoz.

[redacted]

119. On June 1-4, 2014, the HDMA held a Business Leadership Conference ("BLC") at the JW Marriott Desert Ridge in Phoenix, Arizona. The June 1-4, 2014 BLC was attended by the following representatives from all Defendants, including at least the following key executives for generic drug sales and pricing:

a. **Akorn:** Jonathan Kafer, Senior Director, Channel Management;

b. **Sandoz:** Lisa Badura, Director National Accounts – Sales; Anuj Hasija, Key Account Executive Director; Kirko Kirkov, Executive Director, Key Accounts; Ryan Alan, Associate Director, National Accounts; Sean Walsh, Key Account Manager; Della Lubke, Director, National Accounts, Sales; David Picard, VP Generic Sales; Christopher Bihari, Director, National Sales; Steve Greenstein, Director, National Accounts, Sales; and

c. **Impax:** William Ball, Senior National Accounts Manager; Danny Darnell, Senior National Accounts Manager; Todd Engle, Senior Director, Sales Operations; Gary Skalski, Senior Director of Sales.

120. On June 3-4, 2014, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from at least Defendants, Hi-Tech, Fougera, Impax, and Sandoz.

121. On August 23-26, 2014, NACDS held its 2014 Total Store Expo at the Boston Convention Center in Boston, Massachusetts. NACDS's August 2014 Total Store Expo was

attended by the following representatives from all Defendants, including at least the following key executives for generic drug sales and pricing:

a. **Akorn**: Ed Berrios, VP, Sales and Marketing - Hi-Tech Pharmacal Co., Inc.; Michael Corley, VP, National Accounts; Thomas Kronovich, VP, National Accounts; Bruce Kutinsky, Chief Operating Officer; Mick McCanna, Executive Director of National Accounts; Raj Rai Chief, Executive Officer; John Sabat, Senior Vice President of National Accounts; M. Tranter, National Accounts Manager, Sales & Marketing;

b. **Impax:** Chris Gerber, Director of Pricing and Contracts; Italo Pennella, Trade Account Manager; Dan Rozmiarek, Trade Account Manager; and

c. **Sandoz**: Lisa Badura, Director, Key Customers; Christopher Bihari, Director, Key Customers; Steven Greenstein, Director, Key Customers; Anuj Hasija, Executive Director Key Customers; Armondo Kellum, Vice President, Sales and Marketing; Della Lubke, National Account Executive; Scott Smith, VP Sales & Marketing; Arunesh Verma, Executive Director Marketing; Sean Walsh, Director, Key Customers.

122. On October 27-29, 2014, GPhA held its Fall Technical Conference in Bethesda, Maryland that was attended by representatives from at least Defendants Impax, Fougera, and Sandoz.

123. In 2015, and 2016, Defendants continued to regularly attend trade association meetings, conferences and events, including: (i) the February 9-11, 2015 GPhA Annual Meeting in Miami, Florida; [redacted]

(iii) the April 25-28, 2015 NACDS Annual Meeting in Palm Beach, Florida; (iv) the June 7-10, 2015 HDMA BLC in San Antonio, Texas; (v) the June 9-10, 2015 GPhA meeting in Bethesda, Maryland; (vi) the August 22-25, 2015 NACDS Total Store Expo in Denver, Colorado; (vii) the November 2-4, 2015 GPhA meeting in Bethesda, Maryland; (viii) the April 16-19, 2016 NACDS Annual Meeting in Palm Beach, Florida; (ix) the June 12-16, 2016 HDMA BLC in Colorado Springs, Colorado; and (x) the August 6-9, 2016, NACDS 2016 Total Store Expo in Boston, Massachusetts.

124. As uncovered in the State AGs' ongoing investigation, at these various conferences and trade shows, representatives from Defendants, as well as other generic drug manufacturers, discussed their respective businesses and customers. These discussions would occur at social events, including lunches, cocktail parties, dinners, and golf outings, that usually accompanied these conferences and trade shows. Defendants' employees used these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers.[32]

125. In conjunction with meetings at conferences and trade shows, representatives of generic drug manufacturers get together separately, in more limited groups, allowing them to further meet face-to-face with their competitors and discuss their business. In fact, high-level executives of many generic drug manufacturers get together periodically for what at least some of them refer to as "industry dinners."[33]

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[32] *See, e.g.*, Amended Complaint (Public Version), *Connecticut v. Aurobindo Pharma USA, Inc.*, No. 16-cv-2056, ECF 168 (D. Conn.), at ¶¶ 50-52, *available at* http://www.ct.gov/ag/lib/ag/press_releases/2016/20161215_gdms_complain.pdf.

[33] *Id.* at ¶¶ 53-60.

126. A large number of generic drug manufacturers, including Defendants Impax, Hi-Tech, and Sandoz are headquartered or have major offices in close proximity to one another in New Jersey, New York, and eastern Pennsylvania, giving them easier and more frequent opportunities to meet and collude. For example, in January 2014, at a time when the prices of a number of generic drugs were reportedly soaring, at least thirteen high-ranking male executives, including CEOs, Presidents, and Senior Vice Presidents of various generic drug manufacturers, met at a steakhouse in Bridgewater, New Jersey.

127. Generic drug manufacturer employees also get together regularly for what is referred to as a "Girls' Night Out" ("GNO"), or alternatively "Women in the Industry" meetings and dinners. During these GNOs, meetings and dinners, these employees meet with their competitors and discuss competitively sensitive information. For example, several different GNOs were held in 2015, including: (1) in Baltimore, Maryland in May, and (2) at the NACDS conference in August.

128. Through these various interactions, Defendants' employees are often acutely aware of their competition and, more importantly, each other's current and future business plans. This familiarity and opportunity often leads to agreements among competitors to fix prices or to allocate a given market so as to avoid competing with one another on price.

129. Defendants also routinely communicate and share information with each other about bids and pricing strategy. This can include forwarding bid packages received from a customer (*e.g.*, a Request for Proposal or "RFP") to a competitor, either on their own initiative, at the request of a competitor, or by contacting a competitor to request that the competitor share that type of information.

130. Additionally, Defendants share information regarding the terms of their contracts with customers, including various terms relating to pricing, price protection, and rebates. Defendants use this information from their competitors to negotiate potentially better prices or terms with their customers, which could be to the ultimate detriment of consumers.

1. Investor communications demonstrate an intent to fix and maintain supracompetitive prices to realize record profits.

131. Defendants' public statements and admissions in their investor communications show that Defendants realized record revenues during the Class Period and emphasize a commitment to increasing generic pharmaceutical prices as well as maintaining them at supracompetitive levels.

132. **Hi-Tech**: During Hi-Tech's March 7, 2013 earnings call, Hi-Tech CEO David Seltzer stated:

> So we happen to have -- number one, we happen to be doing a significant amount of topicals than -- compared to several years back. So we have the Clobetasol items that we pretty much brought all in-house on the manufacturing side. We have our generic EMLA. We have licensed in a couple of Lidocaine products that are doing very well for us. So we have capacity. And it just happens to be that we were also able to purchase very recently a very high-speed filling and packaging line for creams and ointments that we needed. But that's also going to give us a tremendous amount of capacity going forward. So we are looking very hard to find additional products. We definitely see opportunity. I think everybody knows and understands that there's been some significant price changes in that market over the last couple of years.

133. During Akorn's August 5, 2014 earnings call, Akorn CEO Raj Rai had the following exchange with an analyst:

> Q (analyst): Raj, can you just go into a little bit more detail on the pricing increases on clobetasol. Are you seeing other opportunities across the portfolio, how much of an impact in terms of flow through from that increase are you going to see in the P&L and any pushback that you have heard around that, that would be helpful? Thank you.

> A (Raj Rai, CEO): Randall, this is sort of a new development and with the price increase came some additional contracts and we are in the process of implementing those contracts. So, I think the situation is still little bit fluid and we will have more to discuss in our next conference call when we have fully implemented these new contracts. But the opportunity as it stands is real and it's going to increase our sales substantially in the next quarter. I mean the process has already begun and as Tim mentioned that there are some costs associated with the price increases, so the third quarter would sort of be flat but I think we will start to see the benefit of the price increase and volumes coming through in the fourth quarter. And the question on other products, yes I think there is a general, we are seeing lot of price increases that are happening in the generic space and it affect some of our products as well. So, I would say overall, there is a healthier pricing environment than it was there, I would say six to eight months ago.

134. On November 6, 2014, Rai stated during an earnings call:

> I think prices are stable. And as I said even in my prepared remarks, I think the market dynamics are pretty favorable to generics. And we haven't really seen anything that causes a heartburn or it made a cause of concern as far as pricing is concerned. So I would say, it's a healthy environment.

135. In its annual report for the period ended December 31, 2015, Akorn reported: "Our gross profit increased by $334.7 million, an increase of 128.0% over gross profit of $261.4 million in 2014. Our overall gross profit margin was 60.5% in 2015 compared to 47.1% in 2014." The company attributed the increased profit margin to the effects of "price changes."

136. During Akorn's August 4, 2016 earnings call, Akorn CFO Duane Portwood stated: "net revenue for the quarter ended June 30, 2016, was $281 million, an increase of $60 million or 27% over the prior-year quarter. The increase in revenue was driven by organic growth, with approximately two-thirds attributable to price."

137. Hi-Tech reported rising revenues in its United States generics business during the Class Period.

138. **Impax:** On November 4, 2013, Impax's CFO Bryan Reasons stated during an earnings call that Impax "did take some nice pricing moves" on generic products. During the same call, Impax's President of its Global Pharmaceuticals Division Carole Ben-Maimon stated that it was important generally to "recogniz[e] the potential for price."

139. On a February 20, 2014 Impax earnings call, Ben-Maimon again discussed pricing:

> Obviously, we can't really talk about, for competitive reasons, about specific products with specific prices. But as you've seen across the industry, pricing has improved and the ability to take some price increases has clearly been available. Obviously, we're really careful and we want to make sure that we do that in a very rational way so that we make sure that the price -- that what we're doing sticks and that we actually do make more money in the long run. But we're pretty confident that what we did through towards the end -- throughout the end of last year and the beginning of this year will result in more profitability from many other products that we have been able to take some price on.

140. On a May 2, 2014 Impax earnings call, Reasons noted that a "strong quarter in the generic division" was driven in part by "some pricing initiatives."

141. On an August 6, 2014 Impax earnings call, Ben-Maimon again spoke about pricing:

> Yes. So of course, we look at any opportunity to raise price when it's appropriate. I can't say that -- we didn't talk specifically about specific products here, but we look at our portfolio regularly, if not every single day and look for opportunities in the marketplace to take advantage of services or increased share or price.

Later during the same call, Ben-Maimon mentioned that: "So on pricing, obviously, we don't comment on specific products or what's going on in the market. There are opportunities and we continue to evaluate our portfolio and take advantage where we can."

142. On November 4, 2014, the CEO of Impax Frederick Wilkinson, spoke on pricing:

> [L]et me address pricing. We really don't talk much about pricing publicly, and whether we're going for competitive reasons but surprising to say we've done what most of the other generic competitors have done, we look at opportunities, we look at how competition shifts, we look at where there may be some market movement that will allow us to take advantages on price increases and we've implemented those and we'll continue to evaluate our line product-by-product probably a week and monthly basis to see if there are some opportunities to participate in that practice.

Wilkinson also acknowledged the federal investigation of pricing in the pharmaceutical industry during that earnings call.

143. Impax reported rising revenues in its United States generics business during the Class Period.

144. **Sandoz**: On January 29, 2014, the Division Head of Sandoz Jeffrey George stated:

> So I think overall what I would say is that we've been quite pleased with the acquisition of Fougera [dermatology business]. It is a business that has performed very well for us, with strong double-digit growth and very good margins given the limited competition nature of a lot of these markets.

145. On April 23, 2015, Novartis CEO Joe Jiminez stated that Sandoz had "strong financial results" and "the U.S. was up 13% . . . driven by . . . our Fougera dermatology business."

146. On July 21, 2015, Jiminez stated: "Sandoz delivered very strong financial results with sales and profit up double-digit; as you can see this is driven by the division increased focus on core markets particularly the U.S., which is up 23%."

147. Sandoz reported rising revenues in its United States generics business during the Class Period.

2. Industry commentary indicates collusion is a plausible explanation for the increase in Lidocaine-Prilocaine price

148. Industry analysts agree that generic manufacturers' price hikes are consistent with a price fixing conspiracy. For instance, Richard Evans at Sector & Sovereign Research wrote:

> A plausible explanation [for price increases] is that generic manufacturers, having fallen to near historic low levels of financial performance are cooperating to raise the prices of products whose characteristics – low sales due to either very low prices or very low volumes – accommodate price inflation.[34]

149. According to one study, since 2013 approximately one in 19 generic drugs sold in the United States have undergone major price hikes that may be consistent with collusion:

> Fideres Partners LLP, a London-based consultancy that works with law firms to bring litigation against companies, reported "anomalous pricing patterns" in scores of generic drugs sold in the U.S. from 2013 to 2016. It identified 90 medicines whose prices rose at least 250 percent over the three-year period and were increased by at least two drug companies around the same time, even though there was no obvious market reason for the increases. The average price jump among the 90 drugs was 1,350 percent, Fideres found.
>
> "I don't think the public or even the politicians in the U.S. have any idea just how widespread and extreme the phenomenon is," said Alberto Thomas, one of Fideres's founders.[35]

150. Another study concluded that in 2014, "292 generic medication listings went up by 10% or more, 109 at least doubled in price and 14 went up by ten or more times in price that

[34] *See* Ed Silverman, *Generic Drug Prices Keep Rising, but is a Slowdown Coming?*, WALL STREET JOURNAL (Apr. 22, 2015), *available at* http://blogs.wsj.com/pharmalot/2015/04/22/generic-drug-prices-keep-rising-but-is-a-slowdown-coming/.

[35] Liam Vaughan and Jered S. Hopkins, *Mylan, Teva Led Peers in "Anomalous" Price Moves, Study Says*, BLOOMBERG (Dec. 22, 2016) *available at* https://www.bloomberg.com/news/articles/2016-12-22/widespread-drug-price-increases-point-to-collusion-study-finds.

year."[36] A United States Government Accountability Office ("GAO") report also noted similar "extraordinary price increases" across many generic drugs in recent years that could not be linked to any particular cause.[37]

151. Pennsylvania physicians through the Pennsylvania Medical Society called on state and federal governments to investigate surging generic prices, believing anticompetitive conduct was to blame:

> According to Robert Campbell MD, chair of Physicians Against Drug Shortages and immediate past president of the Pennsylvania Society of Anesthesiologists, surging prices have hit hundreds of mainstay generics, including anesthetics, chemotherapeutic agents, antibiotics, and nutritional intravenous solutions. He believes the surging prices are a result of anti-competitive behavior.[38]

D. Defendants' Conduct in Generic Drug Pricing Is Under Investigation by the United States Congress, the DOJ, and the State Attorneys General.

1. Congress launched an investigation in response to news reports of a dramatic rise in price of certain generic drugs.

152. As noted above, in January 2014 the NCPA sent correspondence to the United States Senate HELP Committee and the United States House Energy and Commerce Committee requesting hearings on significant spikes in generic pharmaceutical pricing.

153. On October 2, 2014, Senator Bernie Sanders (I-VT), Chair of the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, and Representative Elijah E. Cummings (D-MD), the Ranking Member of the House Committee on

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[36] David Belk, MD, *Generic Medication Prices*, *available at* http://truecostofhealthcare.net/generic_medication_prices/.

[37] GAO Report to Congressional Requesters, *Generic Drugs Under Medicare* (Aug. 2016), *available at* http://www.gao.gov/assets/680/679055.pdf.

[38] Pennsylvania Medical Society, Press Release, *Rising Generic Drug costs Have Physicians Raising Red Flags* (Feb. 5, 2016), *available at* http://www.prnewswire.com/news-releases/rising-generic-drug-costs-have-physicians-raising-red-flags-300216006.html.

Oversight and Government Reform, sent letters to 14 drug manufacturers, including Impax's Global Pharmaceuticals division, requesting information about the escalating prices of generic drugs used to treat everything from common medical conditions to life-threatening illnesses.[39]

154. On February 24, 2015, Senator Sanders and Representative Cummings sent a letter requesting that the Office of the Inspector General ("OIG") of the Department of Health and Human Services "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs."[40] The OIG responded to the request on April 13, 2015, advising it would examine pricing for the top 200 generic drugs to "determine the extent to which the quarterly [Average Manufacturer Pricing] exceeded the specified inflation factor."[41]

155. In August 2016, the United States GAO issued its report finding "extraordinary price increases" on many generic pharmaceuticals.[42]

2. The DOJ launched a broad criminal investigation into anticompetitive conduct by generic drug manufacturers.

156. The DOJ opened a criminal investigation into collusion in the generic pharmaceutical industry on or around November 3, 2014. The DOJ also empaneled a grand jury in this District at about the same time.

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[39] U.S. Senator Bernie Sanders Website, Press Release, *Congress Investigating Why Generic Drug Prices Are Skyrocketing* (Oct. 2, 2014), *available at*: https://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.

[40] Letter from Sen. Bernard Sanders & Rep. Elijah E. Cummings, U.S. Cong., to Inspector Gen. Daniel R. Levinson, Dep't of Health & Human Servs. (Feb. 24, 2015), *available at* http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.

[41] Letter from Inspector Gen. Daniel R. Levinson, Dep't of Health & Human Servs., to Sen. Bernard Sanders (Apr. 13, 2015), *available at* http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

[42] GAO Report to Congressional Requesters, *Generic Drugs Under Medicare* (Aug. 2016), *available at* http://www.gao.gov/assets/680/ 679055.pdf.

157. Initial reports suggest that, at the beginning, the DOJ's probe was focused on two generic drugs: digoxin and doxycycline. However, news reports, court filings, and other public statements have confirmed the sweeping nature of the DOJ's investigation. Reportedly, the DOJ believes price-fixing between makers of generic pharmaceuticals is widespread, and its investigation could become the next auto parts investigation, which is the DOJ's largest prosecution to date.[43] According to sources cited by Bloomberg, the DOJ investigation already "spans more than a dozen companies and about two dozen drugs."[44]

158. At least two of the Defendants here have been ensnared in the DOJ's ongoing probe.

159. **Impax**: In **its** July 15, 2014 SEC filing, Impax disclosed that it received a subpoena from the CTAG concerning Impax's sales of generic digoxin and whether it agreed with others to fix prices or allocate customers or territories.[45] In November 2014, Impax further disclosed that one of its sale representatives received a federal grand jury subpoena, requesting testimony and documents about "any communication or correspondence with any competitor (or an employee of any employer) about the sale of generic drugs."[46] The scope of the subpoenas was not limited to a particular drug or a particular timeframe.

160. Impax later disclosed that on March 13, 2015, "the Company received a grand jury subpoena from the Justice Department requesting the production of information and

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[43] Joshua Sisco, *DoJ believes collusion over generic drug prices widespread—source*, POLICY AND REGULATORY REPORT (June 26, 2015), available at: http://www.mergermarket.com/pdf/DoJ-Collusion-Generic-Drug-Prices-2015.pdf.

[44] David McLaughlin and Caroline Chen, *U.S. Charges in Generic Drug Probe to be Filed by Year-End*, BLOOMBERG (Nov. 3, 2016), *available at* https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end.

[45] Impax SEC Form 8-K (July 15, 2014).

[46] Impax SEC Form 8-K (Nov. 6, 2014).

documents regarding the sales, marketing, and pricing of certain generic prescription medications. In particular, the Justice Department's investigation currently focuses on four generic medications: digoxin, terbutaline sulfate tablets, **prilocaine/lidocaine cream,** and calcipotriene topical solution."[47] (emphasis added).

161. **Sandoz**: Sandoz's parent company Novartis reported that: "In March 2016, Sandoz Inc. received a subpoena from the Antitrust Division of the U.S. Department of Justice (DoJ) requesting documents related to the marketing and pricing of generic pharmaceutical products sold by Sandoz Inc. and its subsidiaries, including Fougera Pharmaceuticals, Inc. (Fougera) and related communications with competitors. Sandoz Inc. is cooperating with this investigation which it believes to be part of a broader inquiry into industry practice."[48]

162. Defendants are not alone. Numerous other generic manufacturers have likewise received subpoenas in connection with the DOJ's and the State AGs' broad investigations into anticompetitive conduct in the generic drug industry. Additionally, some of these generic manufacturers have disclosed that search warrants have been executed or that certain employees have been separately subpoenaed as part of these ongoing probes.

163. The fact that these companies received subpoenas from a federal grand jury is significant, as is reflected in Chapter 3 of the 2014 edition of the DOJ's Antitrust Division Manual. Section F.1 of that chapter notes that when deciding whether to request the initiation of a grand jury investigation "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution."[49] The staff request needs to be approved by the

[47] Impax, SEC 2015 Form 10-K (Feb. 22, 2016), at F-53.

[48] Novartis 2016 Annual Report at 217.

[49] DOJ, ANTITRUST DIVISION MANUAL (5th ed. 2015) at III-82.

relevant field chief and is then sent to the Antitrust Criminal Enforcement Division.[50] "The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation."[51] "The investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred."[52]

164. Receipt of federal grand jury subpoenas is an indication that antitrust offenses have occurred.

165. That a target has reportedly applied for leniency is also significant.[53] As the DOJ notes on its web site (http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program):

> **5. Does a leniency applicant have to admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter?**
>
> Yes. The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or

[50] *Id.*

[51] *Id.* at III-83.

[52] *Id.*

[53] Leah Nylen and Josh Sisco, *Generic drug investigation started small before ballooning to dozen companies*, MLEX (Nov. 4, 2016) ("While the Justice Department didn't have a whistleblower at the beginning of the investigation, it is understood that [in the summer of 2016] a company applied for leniency, which grants full immunity to the first company to come forward and admit to cartel violations."), *available at* http://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=841053&siteid=191&rdir=1.

> production volumes, before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will not qualify for leniency through the Leniency Program.

The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials." *Id*.

166. The DOJ's first charges were made on December 12, 2016, against two generic industry executives (Glazer and Malek) with criminal counts related to price collusion for generic doxycycline hyclate and glyburide. *See United States of America v. Jeffrey A. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa.); *United States of America v. Jason T. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa.).

167. These cases allege that these former senior executives of generic drug maker Heritage Pharmaceuticals Inc. violated Section 1 of the Sherman Act by participating in conspiracies to fix prices, rig bids and engage in market and customer allocation concerning generic glyburide and doxycycline. On January 9, 2017, both Glazer and Malek pleaded guilty to the charges. The DOJ charges mention that Glazer and Malek's co-conspirators included "individuals that [Glazer] supervised at his company and those he reported to at his company's parent[.]"[54] Sentencing for both Glazer and Malek was originally set for April 2017 but was later rescheduled to September 2017 as they continue to cooperate with the DOJ. Evidence reportedly unearthed in the State AGs' action shows that Malek compiled a large list of generic drugs and instructed employees to contact competitors to reach agreement to increase prices and

[54] Transcript of Jan. 9, 2017 Plea Hearing, *United States of America v. Jeffrey A. Glazer*, No. 2:16-cr-00506-RBS, ECF 24 at 19 (E.D. Pa.). A similar statement appears in the transcript from Malek's plea hearing.

engage in market and customer allocation, and that some competitors were willing to reach such agreement.

168. The DOJ has intervened in MDL 2724 as well as numerous civil antitrust actions alleging price fixing, bid rigging, and market and customer allocation of generic pharmaceuticals stating that these cases overlap with the DOJ's ongoing criminal investigation. For example, in a civil antitrust action related to the generic pharmaceutical propranolol, the DOJ intervened and requested a stay, stating that "the reason for the request for the stay is the government's ongoing criminal investigation and overlap of that investigation and this case," and that "the government's ongoing investigation is much broader than the [Glazer and Malek] informations that were unsealed."[55] The DOJ filed a brief with the United States Judicial Panel on Multidistrict Litigation noting that, "The complaints in those civil cases – which typically allege that a group of generic pharmaceutical companies violated Section 1 of the Sherman Act by conspiring to fix prices and allocate customers for a particular drug – overlap significantly with aspects of the ongoing criminal investigation."[56] As noted above, the DOJ also filed a motion for a stay of discovery in MDL 2724 stating that: "Evidence uncovered during the criminal investigation implicates other companies and individuals (including a significant number of the Defendants here) in collusion with respect to doxycycline hyclate, glyburide, and other drugs (including a significant number of the drugs at issue here)."[57]

169. The DOJ's Spring 2017 Division Update notes that:

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[55] *See* Transcript of Hearing, *FWK Holdings, LLC v. Actavis Elizabeth, LLC*, No. 16-cv-9901, ECF 112 (S.D.N.Y. Feb. 21, 2017).

[56] *See* Memorandum of Amicus Curiae United States of America Concerning Consolidation, *In re: Generic Digoxin and Doxycycline Antitrust Litig.*, MDL No. 2724, ECF 284 (J.P.M.L. Mar. 10, 2017).

[57] *See* Intervenor United States' Motion to Stay Discovery, *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724, ECF 279 (E.D. Pa. May 1, 2017).

> Millions of Americans purchase generic prescription drugs every year and rely on generic pharmaceuticals as a more affordable alternative to brand name medicines. The Division's investigation into the generics market, however, has revealed that some executives have sought to collude on prices and enrich themselves at the expense of American consumers.[58]

3. Led by the State of Connecticut, 45 state attorneys general launched their own investigation of antitrust violations in the generic drug industry.

170. The State AGs' action was filed just days after the DOJ filed its first criminal charges against two former executives of Heritage Pharmaceuticals. According to the State AGs' complaint, the information developed through its investigation (which is still ongoing) uncovered evidence of a broad, well-coordinated, and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States. Although the State AGs' action currently focuses on doxycycline hyclate and glyburide, it alleges that the State AGs have uncovered a wide-ranging series of conspiracies implicating numerous different generic pharmaceuticals and competitors. As reported by *The Connecticut Mirror*, the CTAG "suspected fraud on a broader, nearly unimaginable scale" and "new subpoenas are going out, and the investigation is growing beyond the companies named in the suit."[59] CTAG George Jepsen has called evidence that has so far been obtained in the State AGs' investigation "mind-boggling."[60]

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[58] DOJ Website, Division Update Spring 2017 (Mar. 28, 2017), *available at* https://www.justice.gov/atr/division-operations/division-update-spring-2017/division-secures-individual-and-corporate-guilty-pleas-collusion-industries-where-products.

[59] Mark Pazniokas, *How a small-state AG's office plays in the big leagues*, The Connecticut Mirror (Jan. 27, 2017), *available at* https://ctmirror.org/2017/01/27/how-a-small-state-ags-office-plays-in-the-big-leagues/. *The Connecticut Mirror* further reported that the DOJ grand jury was convened in this District shortly after the CTAG issued its first subpoena. *Id.*

[60] *Id.*

171. CTAG George Jepsen confirmed the scope of the State AGs' action in the following press release:

> My office has dedicated significant resources to this investigation for more than two years and has developed compelling evidence of collusion and anticompetitive conduct across many companies that manufacture and market generic drugs in the United States. . . . While the principal architect of the conspiracies addressed in this lawsuit was Heritage Pharmaceuticals, we have evidence of widespread participation in illegal conspiracies across the generic drug industry. Ultimately, it was consumers – and, indeed, our healthcare system as a whole – who paid for these actions through artificially high prices for generic drugs. We intend to pursue this and other enforcement actions aggressively, and look forward to working with our colleagues across the country to restore competition and integrity to this important market.[61]

172. In filings with the United States Judicial Panel on Multidistrict Litigation on May 16, 2017 and June 13, 2017, the State AGs reiterated that their ongoing investigation is broad in scope and goes beyond doxycycline hyclate DR and glyburide.[62] The State AGs further stated that their doxycycline hyclate DR and glyburide action "encompass[es] illegal agreements – including with regard to Doxy DR – where prices remained constant (or remained higher than they would have been in a competitive market) as a result of customer or market allocation agreements designed specifically to avoid price erosion[.]" The State AGs also disclosed that they have entered into settlements with Glazer and Malek and that these settlements require Glazer and Malek's cooperation with the State AGs.

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[61] CTAG Website, Press Release, *Connecticut Leads 20 State Coalition Filing Federal Antitrust Lawsuit against Heritage Pharmaceuticals, other Generic Drug Companies* (Dec. 15, 2016), *available at* http://www.ct.gov/ag/cwp/view.asp?Q=588538&A=2341.

[62] *See* Brief and Reply in Support of Plaintiff States' Motion to Vacate Conditional Transfer Order (CTO-3), *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724, ECF 321 & 334 (J.P.M.L. May 16, 2017 & June 13, 2017).

173. During a conference call on July 27, 2017, W. Joseph Nielsen, an assistant AG for the State of Connecticut, said "he expects future actions by the group of states investigating price-fixing and market allocation in the generic drug industry" including "more lawsuits against additional generic manufacturers for additional drugs [and] lawsuits against high-level executives for their roles in the collusion."[63] Nielsen also stated that the States AGs realized very quickly that the generic drug industry is "set up structurally in a way that fosters and promotes collusion among generic competitors" and that the State AGs' investigation "has expanded greatly to the point where we are now looking at numerous drugs."

174. New York AG Eric T. Schneiderman also reported that the State AGs have "uncovered evidence of a broad, well-coordinated and long running series of conspiracies to fix prices and allocate markets for certain generic pharmaceuticals in the United States."[64]

175. The DOJ's and State AGs' investigations of alleged price-fixing and other unlawful conduct in the generic pharmaceutical industry are ongoing.

VI. THE LIDOCAINE-PRILOCAINE MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

176. Because Defendants' anticompetitive conduct constitutes a conspiracy to fix prices and engage in market and customer allocation, which is a *per se* violation of Section 1 of the Sherman Antitrust Act, Plaintiffs need not define a relevant market. However, there are features of the market relevant to this case that show both (i) that the market is susceptible to

[63] Can Calik, *Future actions by state enforcers expected over generic drug collusion, Connecticut official says*, MLEX (July 27, 2017), *available at* http://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=908454&siteid=191&rdir=1.

[64] New York AG Website, Press Release, *A.G. Schneiderman Files Federal Antitrust Lawsuit With 19 Other States Against Heritage Pharmaceuticals And Other Generic Drug Companies* (Dec. 15, 2016), *available at* https://ag.ny.gov/press-release/ag-schneiderman-files-federal-antitrust-lawsuit-19-other-states-against-heritage.

collusion and (ii) that the price increases were in fact the result of collusion and not the result of conscious parallelism.

177. Factors showing that a market is susceptible to collusion include in this case:

(1) **High Level of Industry Concentration** – A small number of competitors (Defendants) control a substantial market share for Lidocaine-Prilocaine, as detailed above. In March 2014, at the outset of the Class Period the Defendants together accounted for roughly [redacted] of the market for these products and did not dip until an authorized generic version began to be sold in or around April 2015, a year after the price increase.

(2) **Sufficient Numbers to Drive Competition** – While the market for Lidocaine-Prilocaine had a small enough number of competitors to foster collusion, the number of sellers was large enough that – given decades of experience with competitive generic pricing, and accepted models of how generic companies vigorously compete on price – one would have expected prices to remain at their historical, near marginal cost levels. With the number of generic competitors such as there were here, historical fact and accepted economics teaches that – absent collusion – prices would have remained at competitive levels.

(3) **High Barriers to Entry** – The high costs of manufacture, intellectual property, development and testing requirements, and lengthy time delay related to regulatory approval and oversight are among the barriers to entry in the generic drug market. For example, the Defendants that controlled virtually all of the Lidocaine-Prilocaine market at the time of the price increase each sold Lidocaine-Prilocaine pursuant to FDA approvals granted years before the price soared. In or around April 2015, Teva began to sell an authorized generic version of Lidocaine-Prilocaine based on FDA-approvals granted many years before its entry. Any other potential new entrant would have to through the lengthy ANDA-approval process before coming to market. The FDA has not approved any ANDA for the sale and marketing of Lidocaine-Prilocaine during the Class Period, there are no other holders of approved ANDAs that have not yet entered the market, and it may take years for the FDA to approve any new ANDA if and when filed. By insulating against new entrants, these barriers to entry and others increase the market's

susceptibility to a coordinated effort among the dominant players to maintain supracompetitive prices.

(4) **High Inelasticity of Demand and Lack of Substitutes** – For the majority of patients who rely on it, Lidocaine-Prilocaine is a necessity that must be purchased regardless of price hikes. While there are other drugs on the market for the anesthetics, there are significant barriers to changing treatments, and both patients and physicians are likely to prioritize medical considerations over price. This makes demand for Lidocaine-Prilocaine highly inelastic.

(5) **Commoditized Market** – Defendants' Lidocaine-Prilocaine products are fully interchangeable because they are bioequivalent to one another by FDA standards. Thus, all manufactured versions of Lidocaine-Prilocaine are therapeutically equivalent to each other and pharmacists may substitute one for another interchangeably.

(6) **Absence of Departures from the Market** – There were no departures from the market that could explain the price increases.

(7) **Absence of Non-Conspiring Competitors** – Defendants controlled virtually all of the market share for Lidocaine-Prilocaine at the time of the price increase and have maintained supracompetitive pricing for Lidocaine-Prilocaine throughout the Class Period. Thus, Defendants have market power in the market for Lidocaine-Prilocaine, which enables them to increase prices without loss of market share to non-conspirators.

(8) **Opportunities for Contact and Communication Among Competitors** – Defendants participate in the committees and events of the GPhA, HDMA, MMCAP, NACDS, ECRM, and other industry groups, which provide and promote opportunities to communicate. The grand jury subpoenas to Defendants targeting inter-Defendant communications, further supports the existence of communication lines between competitors with respect to, among other things, generic pricing.

(9) **Size of Price Increases** – The magnitude of the price increases involved in this case further differentiates them from parallel price increases. Companies seeking to test market increases need to take measured approaches. But here the increases are not 5% or even 10% jumps – the

increases are of far greater magnitude. A rational company would not implement such large increases unless certain that its ostensible competitors would follow.

(10) **Reimbursement of Generic Drugs** – This market, as with many generic markets, has institutional features that would inhibit non-collusive parallel price increases. The reimbursement for generic pharmaceuticals to retail pharmacies is limited by MAC pricing, which is based on the lowest acquisition cost for each generic pharmaceutical paid by retail pharmacies purchasing from a wholesaler for each of a pharmaceutical's generic equivalent versions. As a result, the usual inhibition of a company to unilaterally raise prices is embedded in the generic reimbursement system.

178. Through their market dominance, Defendants have been able to substantially foreclose the market to rival competition, thereby maintaining and enhancing market power and enabling Defendants to charge Plaintiffs and the proposed Class members inflated prices above competitive levels for Lidocaine-Prilocaine through unlawful price collusion.

VII. CLASS ACTION ALLEGATIONS

179. Pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), Plaintiffs bring this action on behalf of a Class defined as:

> All persons or entities that directly purchased Lidocaine-Prilocaine (generic lidocaine-prilocaine cream 2.5-2.5% 30gm) from one or more of the Defendants in the United States and its territories and possessions at any time during the period from March 2014 through the present (the "Class Period").
>
> Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, judicial officers and their personnel, and all governmental entities.

180. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe that there are dozens of Class members, geographically dispersed throughout the United States, such that joinder of all Class members is impracticable. Further, the Class members are readily identifiable from information and records maintained by Defendants.

181. Plaintiffs' claims are typical of, and not antagonistic to, the claims of the other Class members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants.

182. Plaintiffs will fairly and adequately protect and represent the interests of the Class and Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

183. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation.

184. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. Thus, determining damages with respect to the Class as a whole is appropriate. The common applicability of the relevant facts to claims of Plaintiffs and the proposed class is inherent in Defendants' wrongful conduct, because the overcharge injuries incurred by Plaintiffs and each member of the proposed class arose from the same collusive conduct alleged herein.

185. The common legal and factual questions do not vary among Class members and may be determined without reference to individual circumstances, and include, but are not limited to, the following:

(a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby increase the prices of Lidocaine-Prilocaine in the United States;

(b) The duration and extent of the alleged contract, combination, or conspiracy between and among Defendants and their co-conspirators;

(c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;

(d) The effect of the contract, combination, or conspiracy on the prices of Lidocaine-Prilocaine in the United States during the Class Period;

(e) Whether Defendants' conduct caused supracompetitive prices for Lidocaine-Prilocaine;

(f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiffs and other members of the Class; and

(g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

186. Treatment as a class action is the superior method for the fair and efficient adjudication of this controversy, as it will permit numerous similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, avoiding unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding as a class action, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

187. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. ANTITRUST INJURY

188. During the Class Period, Plaintiffs and Class members directly purchased Lidocaine-Prilocaine from Defendants. Because of the Defendants' anticompetitive conduct, Plaintiffs and Class members were forced to pay more for Lidocaine-Prilocaine than they otherwise would have, and thus have suffered substantial overcharge damages at the hands of Defendants. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

189. Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiffs and Class members have sustained, and continue to sustain, significant

losses in the form of artificially inflated prices paid to Defendants. The full amount of such overcharge damages will be calculated after discovery and upon proof at trial.

190. Defendants, through their unlawful conduct alleged herein, reduced competition in the Lidocaine-Prilocaine market, increased prices, reduced choice for purchasers, and caused antitrust injury to purchasers in the form of overcharges.

191. Because Defendants' anticompetitive conduct is ongoing, Plaintiffs and the Class continue to pay supracompetitive prices for Lidocaine-Prilocaine through the present.

IX. CLAIM FOR RELIEF – VIOLATION OF SECTION 1 OF THE SHERMAN ACT

192. Plaintiffs repeat and re-allege the foregoing as though fully set forth herein.

193. In violation of Section 1 of the Sherman Antitrust Act, Defendants entered agreements with one another concerning the pricing of Lidocaine-Prilocaine in the United States. This conspiracy was *per se* unlawful price-fixing.

194. Each of the Defendants has committed at least one overt act to further the conspiracy alleged in this Complaint. Defendants' anticompetitive acts were intentional, were directed at the sales of Lidocaine-Prilocaine in the United States, and had a substantial and foreseeable effect on interstate commerce by raising and fixing Lidocaine-Prilocaine prices throughout the United States.

195. The conspiracy had its intended effect, because Defendants have benefited—and continue to benefit—from their collusion and the elimination of competition, both of which artificially inflated the prices of Lidocaine-Prilocaine.

196. The contract, combination, or conspiracy had the following direct, substantial, and reasonably foreseeable effects upon commerce in the United States:

a. Prices charged to and paid by Plaintiffs for Lidocaine-Prilocaine were artificially raised, fixed, maintained, or stabilized at supracompetitive levels;

b. Plaintiffs were deprived of the benefits of free, open, and unrestricted competition in the sale of Lidocaine-Prilocaine in the United States market; and

c. Competition in establishing the prices paid for Lidocaine-Prilocaine was unlawfully restrained, suppressed, or eliminated.

197. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and Class members have been injured in their business and property in that they have paid more for Lidocaine-Prilocaine than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown and will be determined after discovery and upon proof at trial.

198. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

199. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

200. Defendants' unlawful conduct as alleged herein poses a significant and continuing threat of antitrust injury.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Class members pray for relief from this Court and request:

A. Certification as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiffs as Class Representatives and their counsel of record as Class Counsel;

B. Adjudication that the acts alleged herein constitute unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

C. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiffs and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

D. An award to Plaintiffs and Class members of pre-judgment and post-judgment interest at the highest legal rate provided by law from and after the date of service of the first-filed Complaint in this action;

E. An award to Plaintiffs and Class members of the costs of this suit, including reasonable attorney fees; and

F. An award of any further relief as the Court deems just and proper.

XI. JURY TRIAL DEMANDED

Plaintiffs hereby request a jury trial on all claims so triable.

Dated August 15, 2017

NASTLAW LLC

By: _____
Dianne M. Nast

Dianne M. Nast (PA Bar No. 24424)
Erin C. Burns (PA Bar No. 89742)
1101 Market Street
Suite 2801
Philadelphia, Pennsylvania 19107
215-923-9300
215-923-9302 (fax)
dnast@nastlaw.com
eburns@nastlaw.com

LEAD AND LIAISON COUNSEL

BERGER & MONTAGUE P.C.
David F. Sorensen
Zachary D. Caplan
1622 Locust Street
Philadelphia, Pennsylvania 19103
(215) 875-3000
dsorensen@bm.net
zcaplan@bm.net

KAPLAN FOX & KILSHEIMER LLP
Robert N. Kaplan
Elana Katcher
850 Third Avenue
New York, New York 10022
(212) 687-1980
rkaplan@kaplanfox.com
ekatcher@kaplanfox.com

ROBERTS LAW FIRM P.A.
Michael L. Roberts
Jana K. Law
20 Rahling Circle
Little Rock, Arkansas 72223
(501) 821-5575
mikeroberts@robertslawfirm.us
janalaw@robertslawfirm.us

HAGENS BERMAN SOBOL SHAPIRO LLP
Thomas M. Sobol
David S. Nalven
55 Cambridge Parkway, Suite 301
Cambridge, Massachusetts 02142
617-482-3700
tom@hbsslaw.com
davidn@hbsslaw.com

Barbara A. Mahoney
1918 8th Avenue, Suite 3300
Seattle, Washington 98101
(206) 623-7292
bmahoney@hbsslaw.com

NUSSBAUM LAW GROUP P.C.
Linda P. Nussbaum
Bradley J. Demuth
1211 Avenue of the Americas, 40th Floor
New York, New York 10036
(917) 438-9102
lnussbaum@nusspaumpc.com
bdemuth@nussbaumpc.com

DIRECT PURCHASER PLAINTIFFS' STEERING COMMITTEE

COHEN MILSTEIN SELLERS & TOLL PLLC
Sharon K. Robertson
Donna M. Evans
88 Pine Street, 14th Floor
New York, New York 10005
(212) 838-7797
srobertson@cohenmilstein.com
devans@cohenmilstein.com

FARUQI & FARUQI LLP
Peter Kohn
Joseph T. Lukens
101 Greenwood Avenue, Suite 600
Jenkintown, Pennsylvania 19046
(215) 277-5770
pkohn@faruqilaw.com
jlukens@faruqilaw.com

GUSTAFSON GLUEK PLLC
Daniel E. Gustafson
Daniel C. Hedlund
Canadian Pacific Plaza
120 South 6th Street, Suite 2600
Minneapolis, Minnesota 55402
(612) 333-8844
dgustafson@gustafsongluek.com
dhedlund@gustafsongluek.com

RADICE LAW FIRM
John D. Radice
April D. Lambert
34 Sunset Blvd
Long Beach, New Jersey 08008
(646) 245-8502
jradice@radicelawfirm.com
alambert@radiclawfirm.com

SALTZ MONGELUZZI BARRETT & BENDESKY P.C.
Simon B. Paris
Patrick Howard
One Liberty Place, 52nd Floor
Philadelphia, Pennsylvania 19103
(215) 496-8282
sparis@smbb.com
phoward@smbb.com

TAUS, CEBULASH & LANDAU LLP
Barry S. Taus
Kevin Landau
80 Maiden Lane, Suite 1204
New York, New York 10038
(212) 931-0704
btaus@tcllaw.com
klandau@tcllaw.com

VANEK, VICKERS & MASINI P.C.
Joseph M. Vanek
David P. Germaine
55 West Monroe, Suite 3500
Chicago, Illinois 60603
(312) 224-1500
jvanek@vaneklaw.com
dgermaine@vaneklaw.com

WEXLER WALLACE LLP
Kenneth A. Wexler
Bethany R. Turke
55 West Monroe Street, Suite 3300
Chicago, Illinois 60603
(312) 346-2222
kaw@wexlerwallace.com
brt@wexlerwallace.com

ZIMMERMAN REED LLP
Charles S. Zimmerman
David M. Cialkowski
1100 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402
(612) 341-0400
charles.zimmerman@zimmreed.com
david.cialkowski@zimmreed.com

ADDITIONAL COUNSEL TO DIRECT PURCHASER PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2017, a copy of the Consolidated Direct Purchaser Class Action Complaint was manually filed under seal with the Clerk of the Court and served upon counsel of record via electronic mail.

Dianne M. Nast